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Galephar Pharmaceutical Research, Inc.,  
Cipher Pharmaceuticals Inc.,  
and Sun Pharmaceuticals Industries, Inc.*

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

GALEPHAR PHARMACEUTICAL  
RESEARCH, INC., CIPHER  
PHARMACEUTICALS INC., and SUN  
PHARMACEUTICAL INDUSTRIES, INC.

Plaintiffs,

v.

UPSHER-SMITH LABORATORIES, LLC

Defendant.

C.A. No. \_\_\_\_\_

**PLAINTIFFS GALEPHAR PHARMACEUTICAL RESEARCH, INC.,  
CIPHER PHARMACEUTICALS INC.,  
AND SUN PHARMACEUTICAL INDUSTRIES, INC.'S  
COMPLAINT AGAINST UPSHER-SMITH LABORATORIES, LLC**

Plaintiffs Galephar Pharmaceutical Research, Inc. (“Galephar”), Cipher Pharmaceuticals Inc. (“Cipher”), and Sun Pharmaceutical Industries, Inc. (“Sun”) (together, “Plaintiffs”) for their complaint against defendant Upsher-Smith Laboratories, LLC (“Upsher-Smith”), to the best of their knowledge, information and belief, allege as follows:

### **NATURE OF THE ACTION**

1. This is an action for infringement of United States Patent Nos. 7,435,427 (the “427 patent”); 8,367,102 (the “102 patent”); 8,952,064 (the “064 patent”); 9,078,925 (the “925 patent”); and 9,089,534 (the “534 patent,” collectively, the “patents-in-suit”) under 35 U.S.C. § 271(e)(2) and for Declaratory Judgment of infringement under 28 U.S.C. §§ 2201-02 and 35 U.S.C. § 271(a), (b), and (c) relating to Plaintiffs’ commercially successful products, ABSORICA® (isotretinoin) 10 mg, 20 mg, and 30 mg capsules. This action arises from Defendant’s filing of an Abbreviated New Drug Application (“ANDA”) with the United States Food and Drug Administration (“FDA”) seeking approval to market a generic version of ABSORICA® (isotretinoin) 10 mg, 20 mg, and 30 mg capsules prior to the latest of the expiration dates of the patents-in-suit.

### **THE PARTIES**

2. Plaintiff Galephar is a corporation organized under the laws of Puerto Rico having its principal place of business at Juncos Industrial Park, Juncos, Puerto Rico 00777-3873.

3. Plaintiff Cipher is a corporation organized under the laws of Canada, having its principal place of business at 16-5650 Tomken Road, Mississauga, Ontario, Canada.

4. Plaintiff Sun is an entity organized and existing under the laws of Michigan having a principal place of business at 270 Prospect Plains Road, Cranbury, New Jersey 08512, USA.

5. On information and belief, Defendant Upsher-Smith is a limited liability company organized under the laws of Minnesota having a principal place of business at 6701 Evenstad Drive, Maple Grove, MN 55369.

### **JURISDICTION AND VENUE**

6. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, *et seq.*, and the Declaratory Judgment Act. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

7. Based on the facts alleged herein, this Court has personal jurisdiction over Upsher-Smith.

8. Upsher-Smith has committed an act of patent infringement under 35 U.S.C. §271(e)(2) and intends to manufacture, use, sell, and offer for sale its proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) throughout the United States, including in this district.

9. This Court has personal jurisdiction over Upsher-Smith by virtue of its continuous and systematic contacts with the State of New Jersey, including but not limited to the regular and established place of business Upsher-Smith maintains at 840 Headquarters Plaza, Morristown, NJ 07960. On information and belief, from its regular and established place of business in

Morristown, NJ, Upsher-Smith prepared or made preparations to file ANDA No. 212333 that led to Upsher-Smith's infringement under 35 U.S.C. § 271(e)(2).

10. If ANDA No. 212333 is approved, Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) would be marketed and distributed throughout the United States by Upsher-Smith, including in New Jersey, and/or prescribed by physicians practicing in New Jersey, and dispensed by pharmacies located in New Jersey, all of which would have a substantial effect on commerce.

11. Venue is proper in this district under 28 U.S.C. § 1400(b).

12. Venue is proper in this district under 28 U.S.C. § 1400(b) because Upsher-Smith "committed an act of infringement" in this district and has a "regular place and established place of business" in this district. Upsher-Smith submitted ANDA No. 212333 pursuant to 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), and, upon receiving approval of the ANDA, will manufacture, sell, offer to sell, and/or import its proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) throughout the United States, including in this district. Thus, Upsher-Smith has committed an act of infringement in this district. Upsher-Smith also has a "regular and established place of business" at 840 Headquarters Plaza, Morristown, NJ 07960 where Upsher-Smith conducts business necessary for the manufacture, selling, marketing, and/or importing of its pharmaceutical products.

## **BACKGROUND**

### **The FDA Marketing Approval Process**

13. The FFDCA, 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments, sets forth the rules that the FDA follows when considering the approval of applications for both brand-name and generic drugs.

14. Under the Hatch-Waxman Amendments, an applicant seeking to market a new brand-name drug must prepare a New Drug Application (“NDA”) for consideration by the FDA. *See* 21 U.S.C. § 355.

15. An NDA must include, among other things, the patent number of any patent that claims the drug or a method of using such drug, for which the applicant submitted the NDA and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. §§ 355(b)(1) and (c)(2); 21 C.F.R. §§ 314.53(b) and (c)(2).

16. Upon approval of the NDA, the FDA publishes patent information for the approved drug in its publication, *Approved Drug Products with Therapeutic Equivalence Evaluation*, commonly referred to as the “Orange Book.” *See* 21 U.S.C. § 355(j)(7)(A)(iii).

17. A pharmaceutical company may seek to market a generic version of the innovator’s brand drug by submitting an Abbreviated New Drug Application (“ANDA”) under 21 U.S.C. § 355(j). The generic company may then rely on the studies the innovator includes in its NDA.

**Plaintiffs’ Patents Covering ABSORICA® Isotretinoin Capsules for the Treatment of Severe Recalcitrant Nodular Acne**

18. The U.S. Patent and Trademark Office awarded Galephar each of the five patents-in-suit for its novel formulation that covers Plaintiffs’ commercially successful ABSORICA® isotretinoin capsules for the treatment of severe recalcitrant nodular acne. Patients suffering from severe recalcitrant acne often experience pain, inflammation, and scarring.

**A. The ’427 Patent**

19. On October 14, 2008, the ’427 patent, entitled “Pharmaceutical Semi-Solid Composition of Isotretinoin,” was duly and legally issued by the United States Patent and

Trademark Office (“USPTO”) to inventors Francis Vanderbist, Cecile Servais, and Philippe Baudier. A true and correct copy of the ’427 patent is attached to this complaint as Exhibit A.

20. All inventors of the ’427 patent assigned their interest to Galephar.

21. In February of 2002, Galephar granted Cipher an exclusive right to sell or offer to sell the ABSORICA® isotretinoin capsules.

22. On November 12, 2012 Cipher granted its exclusive right to sell or offer to sell the ABSORICA® isotretinoin capsules to Sun's predecessor in interest, Ranbaxy Pharmaceuticals, Inc.

23. Sun is the owner of the approved NDA No. 021-951 for ABSORICA® (isotretinoin) 10 mg, 20 mg, and 30 mg capsules.

24. In conjunction with NDA No. 021-951, Sun has listed the ’427 patent with the FDA in the Orange Book.

25. ABSORICA® and/or methods of using ABSORICA® are covered by at least one claim of the ’427 patent.

**B. The ’102 Patent**

26. On February 5, 2013, the ’102 patent, entitled “Pharmaceutical Semi-Solid Composition of Isotretinoin,” was duly and legally issued by the United States Patent and Trademark Office (“USPTO”) to inventors Francis Vanderbist, Cecile Servais, and Philippe Baudier. A true and correct copy of the ’102 patent is attached to this complaint as Exhibit B.

27. All inventors of the ’102 patent assigned their interest to Galephar.

28. In February of 2002, Galephar granted Cipher an exclusive right to sell or offer to sell the ABSORICA® isotretinoin capsules.

29. On November 12, 2012 Cipher granted its exclusive right to sell or offer to sell the ABSORICA® isotretinoin capsules to Sun's predecessor in interest, Ranbaxy Pharmaceuticals, Inc.

30. Sun is the owner of the approved NDA No. 021-951 for ABSORICA® (isotretinoin) 10 mg, 20 mg, and 30 mg capsules.

31. In conjunction with NDA No. 021-951, Sun has listed the '102 patent with the FDA in the Orange Book.

32. ABSORICA® and/or methods of using ABSORICA® are covered by at least one claim of the '102 patent.

**C. The '064 Patent**

33. On February 10, 2015, the '064 patent, entitled "Pharmaceutical Semi-Solid Composition of Isotretinoin," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") to inventors Francis Vanderbist, Cecile Servais, and Philippe Baudier. A true and correct copy of the '064 patent is attached to this complaint as Exhibit C.

34. All inventors of the '064 patent assigned their interest to Galephar.

35. In February of 2002, Galephar granted Cipher an exclusive right to sell or offer to sell the ABSORICA® isotretinoin capsules.

36. On November 12, 2012 Cipher granted its exclusive right to sell or offer to sell the ABSORICA® isotretinoin capsules to Sun's predecessor in interest, Ranbaxy Pharmaceuticals, Inc.

37. Sun is the owner of the approved NDA No. 021-951 for ABSORICA® (isotretinoin) 10 mg, 20 mg, and 30 mg capsules.

38. In conjunction with NDA No. 021-951, Sun has listed the '064 patent with the FDA in the Orange Book.

39. ABSORICA® and/or methods of using ABSORICA® are covered by at least one claim of the '064 patent.

**D. The '534 Patent**

40. On July 28, 2015, the '534 patent, entitled "Pharmaceutical Semi-Solid Composition of Isotretinoin," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") to inventors Francis Vanderbist, Cecile Servais, and Philippe Baudier. A true and correct copy of the '534 patent is attached to this complaint as Exhibit D.

41. All inventors of the '534 patent assigned their interest to Galephar.

42. In February of 2002, Galephar granted Cipher an exclusive right to sell or offer to sell the ABSORICA® isotretinoin capsules.

43. On November 12, 2012 Cipher granted its exclusive right to sell or offer to sell the ABSORICA® isotretinoin capsules to Sun's predecessor in interest, Ranbaxy Pharmaceuticals, Inc.

44. Sun is the owner of the approved NDA No. 021-951 for ABSORICA® (isotretinoin) 10 mg, 20 mg, and 30 mg capsules.

45. In conjunction with NDA No. 021-951, Sun has listed the '534 patent with the FDA in the Orange Book.

46. ABSORICA® and/or methods of using ABSORICA® are covered by at least one claim of the '534 patent.



**E. The '925 Patent**

47. On July 14, 2015, the '925 patent, entitled "Pharmaceutical Semi-Solid Composition of Isotretinoin," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") to inventors Arthur M. DeBoeck, Francis Vanderbist, Cecile Servais, and Philippe Baudier. A true and correct copy of the '925 patent is attached to this complaint as Exhibit E.

48. All inventors of the '925 patent assigned their interest to Galephar.

49. In February of 2002, Galephar granted Cipher an exclusive right to sell or offer to sell the ABSORICA® isotretinoin capsules.

50. On November 12, 2012 Cipher granted its exclusive right to sell or offer to sell the ABSORICA® isotretinoin capsules to Sun's predecessor in interest, Ranbaxy Pharmaceuticals, Inc.

51. Sun is the owner of the approved NDA No. 021-951 for ABSORICA® (isotretinoin) 10 mg, 20 mg, and 30 mg capsules.

52. In conjunction with NDA No. 021-951, Sun has listed the '925 patent with the FDA in the Orange Book.

53. ABSORICA® and/or methods of using ABSORICA® are covered by at least one claim of the '925 patent.

**Acts Giving Rise to This Action**

54. Upsher-Smith submitted ANDA No. 212333 under § 505(j) of the FDCA (21 U.S.C. § 355(j)) seeking FDA approval to commercially manufacture, use, offer to sell, or sell a generic version of ABSORICA® (isotretinoin) 10 mg, 20 mg, and 30 mg capsules throughout the United States prior to the latest of the expiration dates of the patents-in-suit.

55. Pursuant to § 505(j)(2)(A)(vii)(IV) of the FFDCA, Upsher-Smith submitted a Paragraph IV Certification in ANDA No. 212333 that alleged that all of the claims of the patents-in-suit are not and would not be infringed by Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg). Upsher-Smith's Paragraph IV certification identifies no factual or legal basis for asserting that that patents-in-suit are invalid or unenforceable.

56. Plaintiffs received written notification of ANDA No. 212333 and Upsher-Smith's allegations under § 505(j)(2)(A)(vii)(IV) on or after December 19, 2018 ("Paragraph IV Notice").

57. The Paragraph IV Notice stated that Upsher-Smith had filed a Paragraph IV Certification with the FDA in conjunction with ANDA No. 212333, which alleged that no valid claim of the patents-in-suit claims will be infringed by Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg).

58. By filing ANDA No. 212333, Upsher-Smith necessarily represented to the FDA that Upsher-Smith's proposed generic isotretinoin capsules have the same active ingredient as ABSORICA® isotretinoin, has the same dosage form and strength as ABSORICA® isotretinoin, and is bioequivalent to ABSORICA® isotretinoin. The Paragraph IV Notice stated that Upsher-Smith's ANDA filing contains any required bioavailability or bioequivalence data.

59. On information and belief, Upsher-Smith is seeking approval to market its proposed generic isotretinoin capsules for the same approved indication as ABSORICA® isotretinoin.

60. Upsher-Smith provided its Offer of Confidential Access ("OCA") to ANDA No. 212333 under 21 U.S.C. § 355(j)(5)(C)(i)(III) and on the terms and conditions set forth in the

Paragraph IV Notice. Upsher-Smith requested that Plaintiffs accept the OCA before receiving access to Upsher-Smith's ANDA. Under 21 U.S.C. § 355(j)(5)(C)(i)(III), an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information." The OCA contained unreasonable restrictions, above and beyond those that would apply under a protective order, on who could view the ANDA. For example, the OCA limited access to outside counsel from one law firm for Sun and one law firm for Galephar, and did not permit Plaintiffs to share the ANDA with in-house counsel, in-house scientists, or independent experts. The OCA further unreasonably limited the fields of practice and other activities of outside counsel and any other person who accepted access to the ANDA. The OCA also did not provide access to the full ANDA filed with the FDA, but instead only offered unidentified portions of the ANDA selected solely by Upsher-Smith. The OCA further did not provide access to Upsher-Smith's Drug Master File or correspondence with the FDA post-dating the filing of the ANDA.

61. After receiving the Paragraph IV Notice, Plaintiffs and Upsher-Smith negotiated in good faith, but were unable to reach a mutually-acceptable agreement under which Upsher-Smith would provide its ANDA to Plaintiffs. Upsher-Smith's final proposal still limited Plaintiffs' abilities to share the ANDA with their in-house legal representatives. Upsher-Smith's proposal also continued to unreasonably limit the fields of practice and other activities of any person, including outside counsel, who accepts access to the ANDA. For example, Upsher-Smith's proposal contained an unreasonably overbroad restriction on FDA practice, barring both in-house and outside counsel who accessed Upsher-Smith's ANDA from directly, indirectly, formally, or informally being involved in preparing any submission to the FDA relating to any

isotretinoin drug product. As a result, Plaintiffs have been unable to access Upsher-Smith's ANDA.

62. Under the Hatch-Waxman Act, an owner of a patented drug must file an action in federal court within 45 days of receiving a Paragraph IV letter in order to receive certain benefits under the Act, including a stay of approval of the generic drug for up to 30 months during the pendency of litigation, as appropriate. *See* 21 U.S.C. § 355(c)(3)(c).

63. Plaintiffs are not aware of any other means of obtaining information regarding Upsher-Smith's proposed generic isotretinoin capsules within the 45-day statutory period. In the absence of such information, Plaintiffs resort to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to confirm their belief and to present to the Court evidence that Upsher-Smith infringes certain claims of the patents-in-suit. The Federal Circuit has recognized this course of conduct as reasonable. *See Hoffmann-La Roche, Inc. v. Invamed Inc.*, 213 F.3d 1359, 1363-64 (Fed. Cir. 2000).

64. This action is being commenced before the expiration of 45 days from the date Plaintiffs received the Paragraph IV Notice, which triggers a stay of FDA approval of Upsher-Smith's ANDA No. 212333, pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

65. Upsher-Smith has made, and continues to make, substantial preparation to manufacture, offer to sell, sell and/or import its proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg).

66. Upsher-Smith's actions, including, but not limited to, the development of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) and the filing of ANDA No. 212333 with a Paragraph IV Certification, indicate a continued course of conduct to

seek FDA approval of ANDA No. 212333 and to manufacture, market, and sell the product after such approval.

**COUNT I**

**(Infringement of U.S. Patent No. 7,435,427 Under 35 U.S.C. § 271(e)(2)(A) by Upsher-Smith's Proposed Generic Isotretinoin Capsules, USP (10 mg, 20 mg, and 30 mg))**

67. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

68. Upsher-Smith submitted ANDA No. 212333 to the FDA under section 505(j) of the FFDCA to obtain approval to engage in the manufacture, use or sale throughout the United States, of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) prior to the latest of the expiration dates of the patents-in-suit. By submitting ANDA No. 212333, Upsher-Smith has committed an act of infringement of U.S. Patent No. 7,435,427 ("the '427 patent") under 35 U.S.C. § 271(e)(2)(A).

69. The commercial manufacture, use, offer for sale, sale, and/or importation of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) prior to the expiration date of the '427 patent will constitute an act of infringement of the '427 patent.

70. On information and belief, Upsher-Smith became aware of the '427 patent no later than the date on which that patent was listed in the Orange Book.

71. On information and belief, Upsher-Smith knows or should know that its commercial manufacture, use, offer for sale, sale and/or importation of its proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will actively induce and contribute to the actual infringement of the '427 patent.

72. On information and belief, Upsher-Smith knows or should know that Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will be especially made for or especially adapted for use in infringement of the '427 patent, and are not

staple articles or commodities of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will actively contribute to the actual infringement of the '427 patent.

73. The commercial manufacture, use, offer for sale, sale and/or importation of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

74. Plaintiffs do not have an adequate remedy at law and will be irreparably harmed by Upsher-Smith's infringing conduct unless such conduct is enjoined by this Court.

## **COUNT II**

### **(Declaratory Judgment of Infringement of the '427 Patent Under U.S.C. § 271(a) by Upsher-Smith's Proposed Generic Isotretinoin Capsules, USP (10 mg, 20 mg, and 30))**

75. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

76. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

77. An actual case or controversy between Plaintiffs and Upsher-Smith exists such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution.

78. Upsher-Smith has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell and/or import its proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg).

79. Upsher-Smith's recent actions indicate that they do not intend to change their course of conduct.

80. Any manufacture, use, offer for sale, sale and/or importation of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) prior to the expiration of the '427 patent will constitute direct infringement of the '427 patent.

81. Plaintiffs are entitled to a declaratory judgment that any manufacture, use, offer for sale, sale and/or importation of the proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) by Upsher-Smith prior to the expiration of the '427 patent will constitute direct infringement of said patent.

82. On information and belief, despite having actual notice of the '427 patent, Upsher-Smith continues to willfully, wantonly, and deliberately prepare to infringe the '427 patent in disregard of Plaintiffs' rights, making this case exceptional and entitling Plaintiffs to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

### **COUNT III**

#### **(Declaratory Judgment of Infringement of the '427 Patent Under U.S.C. § 271(b) and (c) by Upsher-Smith's Proposed Generic Isotretinoin Capsules, USP (10 mg, 20 mg, and 30))**

83. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

84. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

85. An actual case or controversy between Plaintiffs and Upsher-Smith exists such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution.

86. Upsher-Smith has actual knowledge of the '427 patent.

87. On information and belief, Upsher-Smith became aware of the '427 patent no later than the date on which that patent was listed in the Orange Book.

88. On information and belief, Upsher-Smith has acted with full knowledge of the '427 patent and without a reasonable basis for believing that Upsher-Smith would not be liable for actively inducing or contributing to the infringement of the '427 patent.

89. The commercial manufacture, use, sale, offer for sale, and/or importation of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will induce the actual infringement of the '427 patent.

90. On information and belief, Upsher-Smith knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will actively induce the actual infringement of the '427 patent.

91. On information and belief, Upsher-Smith will encourage another's infringement of the '427 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg), which are covered by the claims of the '427 patent.

92. Upsher-Smith's acts of infringement will be done with knowledge of the '427 patent and with the intent to encourage infringement.

93. The foregoing actions by Upsher-Smith will constitute active inducement of infringement of the '427 patent.

94. On information and belief, Upsher-Smith knows or should know that Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will be



especially made or especially adapted for use in an infringement of the '427 patent, and are not staple articles or commodities of commerce suitable for substantial non-infringing use.

95. The commercial manufacture, use, sale, offer for sale, and/or importation of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will contribute to the actual infringement of the '427 patent.

96. On information and belief, Upsher-Smith knows or should know that Upsher-Smith's offer for sale, sale and/or importation of its proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will contribute to the actual infringement of the '427 patent.

97. The foregoing actions by Upsher-Smith will constitute contributory infringement of the '427 patent.

98. On information and belief, Upsher-Smith intends to, and will, actively induce and contribute to the infringement of the '427 patent when ANDA No. 212333 is approved, and plans and intends to, and will, do so immediately and imminently upon final approval.

99. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) by Upsher-Smith will induce and/or contribute to infringement of the '427 patent.

100. The commercial manufacture, use, offer for sale, sale and/or importation of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg), which will actively induce and/or contribute to infringement of the '427 patent, in violation of Plaintiffs' patent rights, will cause harm to Plaintiffs for which damages are inadequate.

101. Unless Upsher-Smith is enjoined from actively inducing and contributing to the infringement of the '427 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

102. On information and belief, despite having actual notice of the '427 patent, Upsher-Smith continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '427 patent in disregard of Plaintiffs' rights, making this case exceptional and entitling Plaintiffs to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

#### **COUNT IV**

#### **(Infringement of U.S. Patent No. 8,367,102 Under 35 U.S.C. § 271(e)(2)(A) by Upsher-Smith's Proposed Generic Isotretinoin Capsules, USP (10 mg, 20 mg, and 30 mg))**

103. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

104. Upsher-Smith submitted ANDA No. 212333 to the FDA under section 505(j) of the FFDCA to obtain approval to engage in the manufacture, use or sale throughout the United States, of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) prior to the latest of the expiration dates of the patents-in-suit. By submitting ANDA No. 212333, Upsher-Smith has committed an act of infringement of U.S. Patent No. 8,367,102 ("the '102 patent") under 35 U.S.C. § 271(e)(2)(A).

105. The commercial manufacture, use, offer for sale, sale, and/or importation of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) prior to the expiration date of the '102 patent will constitute an act of infringement of the '102 patent.

106. On information and belief, Upsher-Smith became aware of the '102 patent no later than the date on which that patent was listed in the Orange Book.

107. On information and belief, Upsher-Smith knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will actively induce and contribute to the actual infringement of the '102 patent.

108. On information and belief, Upsher-Smith knows or should know that Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will be especially made for or especially adapted for use in infringement of the '102 patent, and are not staple articles or commodities of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will actively contribute to the actual infringement of the '102 patent.

109. The commercial manufacture, use, offer for sale, sale and/or importation of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

110. Plaintiffs do not have an adequate remedy at law and will be irreparably harmed by Upsher-Smith's infringing conduct unless such conduct is enjoined by this Court.

#### **COUNT V**

#### **(Declaratory Judgment of Infringement of the '102 Patent Under U.S.C. § 271(a) by Upsher-Smith's Proposed Generic Isotretinoin Capsules, USP (10 mg, 20 mg, and 30))**

111. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

112. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

113. An actual case or controversy between Plaintiffs and Upsher-Smith exists such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution.

114. Upsher-Smith has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell and/or import its proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg).

115. Upsher-Smith's recent actions indicate that they do not intend to change their course of conduct.

116. Any manufacture, use, offer for sale, sale and/or importation of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) prior to the expiration of the '102 patent will constitute direct infringement of the '102 patent.

117. Plaintiffs are entitled to a declaratory judgment that any manufacture, use, offer for sale, sale and/or importation of the proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) by Upsher-Smith prior to the expiration of the '102 patent will constitute direct infringement of said patent.

118. On information and belief, despite having actual notice of the '102 patent, Upsher-Smith continues to willfully, wantonly, and deliberately prepare to infringe the '102 patent in disregard of Plaintiffs' rights, making this case exceptional and entitling Plaintiff to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

**COUNT VI**

**(Declaratory Judgment of Infringement of the '102 Patent Under U.S.C. § 271(b) and (c) by Upsher-Smith's Proposed Generic Isotretinoin Capsules, USP (10 mg, 20 mg, and 30))**

119. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

120. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

121. An actual case or controversy between Plaintiffs and Upsher-Smith exists such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution.

122. Upsher-Smith has actual knowledge of the '102 patent.

123. On information and belief, Upsher-Smith became aware of the '102 patent no later than the date on which that patent was listed in the Orange Book.

124. On information and belief, Upsher-Smith has acted with full knowledge of the '102 patent and without a reasonable basis for believing that Upsher-Smith would not be liable for actively inducing or contributing to the infringement of the '102 patent.

125. The commercial manufacture, use, sale, offer for sale, and/or importation of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will induce the actual infringement of the '102 patent.

126. On information and belief, Upsher-Smith knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will actively induce the actual infringement of the '102 patent.

127. On information and belief, Upsher-Smith will encourage another's infringement of the '102 patent by and through the commercial manufacture, use, sale, offer for sale, and/or

importation of its proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg), which are covered by the claims of the '102 patent.

128. Upsher-Smith's acts of infringement will be done with knowledge of the '102 patent and with the intent to encourage infringement.

129. The foregoing actions by Upsher-Smith will constitute active inducement of infringement of the '102 patent.

130. On information and belief, Upsher-Smith knows or should know that Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will be especially made or especially adapted for use in an infringement of the '102 patent, and are not staple articles or commodities of commerce suitable for substantial non-infringing use.

131. The commercial manufacture, use, sale, offer for sale, and/or importation of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will contribute to the actual infringement of the '102 patent.

132. On information and belief, Upsher-Smith knows or should know that Upsher-Smith's offer for sale, sale and/or importation of its proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will contribute to the actual infringement of the '102 patent.

133. The foregoing actions by Upsher-Smith will constitute contributory infringement of the '102 patent.

134. On information and belief, Upsher-Smith intends to, and will, actively induce and contribute to the infringement of the '102 patent when ANDA No. 212333 is approved, and plan and intend to, and will, do so immediately and imminently upon final approval.

135. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Upsher-Smith's proposed generic

isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) by Upsher-Smith will induce and/or contribute to infringement of the '102 patent.

136. The commercial manufacture, use, offer for sale, sale and/or importation of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg), which will actively induce and/or contribute to infringement of the '102 patent, in violation of Plaintiffs' patent rights, will cause harm to Plaintiffs for which damages are inadequate.

137. Unless Upsher-Smith is enjoined from actively inducing and contributing to the infringement of the '102 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

138. On information and belief, despite having actual notice of the '102 patent, Upsher-Smith continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '102 patent in disregard of Plaintiffs' rights, making this case exceptional and entitling Plaintiffs to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

#### **COUNT VII**

#### **(Infringement of U.S. Patent No. 8,952,064 Under 35 U.S.C. § 271(e)(2)(A) by Upsher-Smith's Proposed Generic Isotretinoin Capsules, USP (10 mg, 20 mg, and 30 mg))**

139. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

140. Upsher-Smith submitted ANDA No. 212333 to the FDA under section 505(j) of the FFDCA to obtain approval to engage in the manufacture, use or sale throughout the United States, of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) prior to the latest of the expiration dates of the patents-in-suit. By submitting ANDA No. 212333, Upsher-Smith has committed an act of infringement of U.S. Patent No. 8,952,064 ("the '064 patent") under 35 U.S.C. § 271(e)(2)(A).

141. The commercial manufacture, use, offer for sale, sale, and/or importation of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) prior to the expiration date of the '064 patent will constitute an act of infringement of the '064 patent.

142. On information and belief, Upsher-Smith became aware of the '064 patent no later than the date on which that patent was listed in the Orange Book.

143. On information and belief, Upsher-Smith knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will actively induce and contribute to the actual infringement of the '064 patent.

144. On information and belief, Upsher-Smith knows or should know that Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will be especially made for or especially adapted for use in infringement of the '064 patent, and are not staple articles or commodities of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will actively contribute to the actual infringement of the '064 patent.

145. The commercial manufacture, use, offer for sale, sale and/or importation of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

146. Plaintiffs do not have an adequate remedy at law and will be irreparably harmed by Upsher-Smith's infringing conduct unless such conduct is enjoined by this Court.



**COUNT VIII**

**(Declaratory Judgment of Infringement of the '064 Under U.S.C. § 271(a) by Upsher-Smith's Proposed Generic Isotretinoin Capsules, USP (10 mg, 20 mg, and 30))**

147. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

148. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

149. An actual case or controversy between Plaintiffs and Upsher-Smith exists such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution.

150. Upsher-Smith has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell and/or import its proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg).

151. Upsher-Smith's recent actions indicate that they do not intend to change their course of conduct.

152. Any manufacture, use, offer for sale, sale and/or importation of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) prior to the expiration of the '064 patent will constitute direct infringement of the '064 patent.

153. Plaintiffs are entitled to a declaratory judgment that any manufacture, use, offer for sale, sale and/or importation of the proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) by Upsher-Smith prior to the expiration of the '064 patent will constitute direct infringement of said patent.

154. On information and belief, despite having actual notice of the '064 patent, Upsher-Smith continues to willfully, wantonly, and deliberately prepare to infringe the '064

patent in disregard of Plaintiffs' rights, making this case exceptional and entitling Plaintiffs to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

**COUNT IX**

**(Declaratory Judgment of Infringement of the '064 Patent Under U.S.C. § 271(b) and (c) by  
Upsher-Smith's Proposed Generic Isotretinoin Capsules, USP (10 mg, 20 mg, and 30))**

155. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

156. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

157. An actual case or controversy between Plaintiffs and Upsher-Smith exists such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution.

158. Upsher-Smith has actual knowledge of the '064 patent.

159. On information and belief, Upsher-Smith became aware of the '064 patent no later than the date on which that patent was listed in the Orange Book.

160. On information and belief, Upsher-Smith has acted with full knowledge of the '064 patent and without a reasonable basis for believing that Upsher-Smith would not be liable for actively inducing or contributing to the infringement of the '064 patent.

161. The commercial manufacture, use, sale, offer for sale, and/or importation of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will induce the actual infringement of the '064 patent.

162. On information and belief, Upsher-Smith knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic

isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will actively induce the actual infringement of the '064 patent.

163. On information and belief, Upsher-Smith will encourage another's infringement of the '064 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg), which are covered by the claims of the '064 patent.

164. Upsher-Smith's acts of infringement will be done with knowledge of the '064 patent and with the intent to encourage infringement.

165. The foregoing actions by Upsher-Smith will constitute active inducement of infringement of the '064 patent.

166. On information and belief, Upsher-Smith knows or should know that Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will be especially made or especially adapted for use in an infringement of the '064 patent, and are not staple articles or commodities of commerce suitable for substantial non-infringing use.

167. The commercial manufacture, use, sale, offer for sale, and/or importation of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will contribute to the actual infringement of the '064 patent.

168. On information and belief, Upsher-Smith knows or should know that Upsher-Smith's offer for sale, sale and/or importation of its proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will contribute to the actual infringement of the '064 patent.

169. The foregoing actions by Upsher-Smith will constitute contributory infringement of the '064 patent.

170. On information and belief, Upsher-Smith intends to, and will, actively induce and contribute to the infringement of the '064 patent when ANDA No. 212333 is approved, and plan and intend to, and will, do so immediately and imminently upon final approval.

171. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) by Upsher-Smith will induce and/or contribute to infringement of the '064 patent.

172. The commercial manufacture, use, offer for sale, sale and/or importation of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg), which will actively induce and/or contribute to infringement of the '064 patent, in violation of Plaintiffs' patent rights, will cause harm to Plaintiffs for which damages are inadequate.

173. Unless Upsher-Smith is enjoined from actively inducing and contributing to the infringement of the '064 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

174. On information and belief, despite having actual notice of the '064 patent, Upsher-Smith continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '064 patent in disregard of Plaintiffs' rights, making this case exceptional and entitling Plaintiffs to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

**COUNT X**

**(Infringement of U.S. Patent No. 9,078,925 Under 35 U.S.C. § 271(e)(2)(A) by Upsher-Smith's Proposed Generic Isotretinoin Capsules, USP (10 mg, 20 mg, and 30 mg))**

175. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

176. Upsher-Smith submitted ANDA No. 212333 to the FDA under section 505(j) of the FFDCA to obtain approval to engage in the manufacture, use or sale throughout the United States, of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) prior to the latest of the expiration dates of the patents-in-suit. By submitting ANDA No. 212333, Upsher-Smith has committed an act of infringement of U.S. Patent No. 9,078,925 ("the '925 patent") under 35 U.S.C. § 271(e)(2)(A).

177. The commercial manufacture, use, offer for sale, sale, and/or importation of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) prior to the expiration date of the '925 patent will constitute an act of infringement of the '925 patent.

178. On information and belief, Upsher-Smith became aware of the '925 patent no later than the date on which that patent was listed in the Orange Book.

179. On information and belief, Upsher-Smith knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will actively induce and contribute to the actual infringement of the '925 patent.

180. On information and belief, Upsher-Smith knows or should know that Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will be especially made for or especially adapted for use in infringement of the '925 patent, and are not staple articles or commodities of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic

isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will actively contribute to the actual infringement of the '925 patent.

181. The commercial manufacture, use, offer for sale, sale and/or importation of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) in violation of Plaintiffs' patent rights will cause harm to Plaintiff for which damages are inadequate.

182. Plaintiffs do not have an adequate remedy at law and will be irreparably harmed by Upsher-Smith's infringing conduct unless such conduct is enjoined by this Court.

#### **COUNT XI**

#### **(Declaratory Judgment of Infringement of the '925 Patent Under U.S.C. § 271(a) by Upsher-Smith's Proposed Generic Isotretinoin Capsules, USP (10 mg, 20 mg, and 30))**

183. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

184. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

185. An actual case or controversy between Plaintiffs and Upsher-Smith exists such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution.

186. Upsher-Smith has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell and/or import its proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg).

187. Upsher-Smith's recent actions indicate that they do not intend to change their course of conduct.

188. Any manufacture, use, offer for sale, sale and/or importation of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) prior to the expiration of the '925 patent will constitute direct infringement of the '925 patent.

189. Plaintiffs are entitled to a declaratory judgment that any manufacture, use, offer for sale, sale and/or importation of the proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) by Upsher-Smith prior to the expiration of the '925 patent will constitute direct infringement of said patent.

190. On information and belief, despite having actual notice of the '925 patent, Upsher-Smith continues to willfully, wantonly, and deliberately prepare to infringe the '925 patent in disregard of Plaintiffs' rights, making this case exceptional and entitling Plaintiff to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

## **COUNT XII**

### **(Declaratory Judgment of Infringement of the '925 Patent Under U.S.C. § 271(b) and (c) by Upsher-Smith's Proposed Generic Isotretinoin Capsules, USP (10 mg, 20 mg, and 30))**

191. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

192. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

193. An actual case or controversy between Plaintiffs and Upsher-Smith exists such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution.

194. Upsher-Smith has actual knowledge of the '925 patent.

195. On information and belief, Upsher-Smith became aware of the '925 patent no later than the date on which that patent was listed in the Orange Book.

196. On information and belief, Upsher-Smith has acted with full knowledge of the '925 patent and without a reasonable basis for believing that Upsher-Smith would not be liable for actively inducing or contributing to the infringement of the '925 patent.

197. The commercial manufacture, use, sale, offer for sale, and/or importation of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will induce the actual infringement of the '925 patent.

198. On information and belief, Upsher-Smith knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will actively induce the actual infringement of the '925 patent.

199. On information and belief, Upsher-Smith will encourage another's infringement of the '925 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg), which are covered by the claims of the '925 patent.

200. Upsher-Smith's acts of infringement will be done with knowledge of the '925 patent and with the intent to encourage infringement.

201. The foregoing actions by Upsher-Smith will constitute active inducement of infringement of the '925 patent.

202. On information and belief, Upsher-Smith knows or should know that Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will be especially made or especially adapted for use in an infringement of the '925 patent, and are not staple articles or commodities of commerce suitable for substantial non-infringing use.



203. The commercial manufacture, use, sale, offer for sale, and/or importation of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will contribute to the actual infringement of the '925 patent.

204. On information and belief, Upsher-Smith knows or should know that Upsher-Smith's offer for sale, sale and/or importation of its proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will contribute to the actual infringement of the '925 patent.

205. The foregoing actions by Upsher-Smith will constitute contributory infringement of the '925 patent.

206. On information and belief, Upsher-Smith intends to, and will, actively induce and contribute to the infringement of the '925 patent when ANDA No. 212333 is approved, and plan and intend to, and will, do so immediately and imminently upon final approval.

207. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) by Upsher-Smith will induce and/or contribute to infringement of the '925 patent.

208. The commercial manufacture, use, offer for sale, sale and/or importation of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg), which will actively induce and/or contribute to infringement of the '925 patent, in violation of Plaintiffs' patent rights, will cause harm to Plaintiffs for which damages are inadequate.

209. Unless Upsher-Smith is enjoined from actively inducing and contributing to the infringement of the '925 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

210. On information and belief, despite having actual notice of the '925 patent, Upsher-Smith continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '925 patent in disregard of Plaintiffs' rights, making this case exceptional and entitling Plaintiffs to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

**COUNT XIII**

**(Infringement of U.S. Patent No. 9,089,534 Under 35 U.S.C. § 271(e)(2)(A) by Upsher-Smith's Proposed Generic Isotretinoin Capsules, USP (10 mg, 20 mg, and 30 mg))**

211. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

212. Upsher-Smith submitted ANDA No. 212333 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the manufacture, use or sale throughout the United States, of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) prior to the latest of the expiration dates of the patents-in-suit. By submitting ANDA No. 212333, Upsher-Smith has committed an act of infringement of U.S. Patent No. 9,089,534 ("the '534 patent") under 35 U.S.C. § 271(e)(2)(A).

213. The commercial manufacture, use, offer for sale, sale, and/or importation of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) prior to the expiration date of the '534 patent will constitute an act of infringement of the '534 patent.

214. On information and belief, Upsher-Smith became aware of the '534 patent no later than the date on which that patent was listed in the Orange Book.

215. On information and belief, Upsher-Smith knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will actively induce and contribute to the actual infringement of the '534 patent.

216. On information and belief, Upsher-Smith knows or should know that Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will be especially made for or especially adapted for use in infringement of the '534 patent, and are not staple articles or commodities of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will actively contribute to the actual infringement of the '534 patent.

217. The commercial manufacture, use, offer for sale, sale and/or importation of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

218. Plaintiffs do not have an adequate remedy at law and will be irreparably harmed by Upsher-Smith's infringing conduct unless such conduct is enjoined by this Court.

#### **COUNT XIV**

#### **(Declaratory Judgment of Infringement of the '534 Patent Under U.S.C. § 271(a) by Upsher-Smith's Proposed Generic Isotretinoin Capsules, USP (10 mg, 20 mg, and 30))**

219. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

220. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

221. An actual case or controversy between Plaintiffs and Upsher-Smith exists such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution.

222. Upsher-Smith has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell and/or import its proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg).

223. Upsher-Smith's recent actions indicate that they do not intend to change their course of conduct.

224. Any manufacture, use, offer for sale, sale and/or importation of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) prior to the expiration of the '534 patent will constitute direct infringement of the '534 patent.

225. Plaintiffs are entitled to a declaratory judgment that any manufacture, use, offer for sale, sale and/or importation of the proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) by Upsher-Smith prior to the expiration of the '534 patent will constitute direct infringement of said patent.

226. On information and belief, despite having actual notice of the '534 patent, Upsher-Smith continues to willfully, wantonly, and deliberately prepare to infringe the '534 patent in disregard of Plaintiffs' rights, making this case exceptional and entitling Plaintiffs to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

#### **COUNT XV**

#### **(Declaratory Judgment of Infringement of the '534 Patent Under U.S.C. § 271(b) and (c) by Upsher-Smith's Proposed Generic Isotretinoin Capsules, USP (10 mg, 20 mg, and 30))**

227. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

228. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

229. An actual case or controversy between Plaintiffs and Upsher-Smith exists such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution.

230. Upsher-Smith has actual knowledge of the '534 patent.

231. On information and belief, Upsher-Smith became aware of the '534 patent no later than the date on which that patent was listed in the Orange Book.

232. On information and belief, Upsher-Smith has acted with full knowledge of the '534 patent and without a reasonable basis for believing that Upsher-Smith would not be liable for actively inducing or contributing to the infringement of the '534 patent.

233. The commercial manufacture, use, sale, offer for sale, and/or importation of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will induce the actual infringement of the '534 patent.

234. On information and belief, Upsher-Smith knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will actively induce the actual infringement of the '534 patent.

235. On information and belief, Upsher-Smith will encourage another's infringement of the '534 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg), which are covered by the claims of the '534 patent.

236. Upsher-Smith's acts of infringement will be done with knowledge of the '534 patent and with the intent to encourage infringement.

237. The foregoing actions by Upsher-Smith will constitute active inducement of infringement of the '534 patent.

238. On information and belief, Upsher-Smith knows or should know that Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will be especially made or especially adapted for use in an infringement of the '534 patent, and are not staple articles or commodities of commerce suitable for substantial non-infringing use.

239. The commercial manufacture, use, sale, offer for sale, and/or importation of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will contribute to the actual infringement of the '534 patent.

240. On information and belief, Upsher-Smith knows or should know that Upsher-Smith's offer for sale, sale and/or importation of its proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) will contribute to the actual infringement of the '534 patent.

241. The foregoing actions by Upsher-Smith will constitute contributory infringement of the '534 patent.

242. On information and belief, Upsher-Smith intends to, and will, actively induce and contribute to the infringement of the '534 patent when ANDA No. 212333 is approved, and plan and intend to, and will, do so immediately and imminently upon final approval.

243. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) by Upsher-Smith will induce and/or contribute to infringement of the '534 patent.

244. The commercial manufacture, use, offer for sale, sale and/or importation of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg), which

will actively induce and/or contribute to infringement of the '534 patent, in violation of Plaintiffs' patent rights, will cause harm to Plaintiffs for which damages are inadequate.

245. Unless Upsher-Smith is enjoined from actively inducing and contributing to the infringement of the '534 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

246. On information and belief, despite having actual notice of the '534 patent, Upsher-Smith continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '534 patent in disregard of Plaintiffs' rights, making this case exceptional and entitling Plaintiffs to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

### **PRAYER FOR RELIEF**

Plaintiffs respectfully pray for the following relief:

- a. That judgment be entered that Upsher-Smith has infringed the patents-in-suit under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 212333 under the FDCA, and that the commercial manufacture, use, offer for sale, sale and/or importation of Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) prior to expiry of the latest expiration date of the patents-in-suit will constitute an act of infringement of the patents-in-suit;
- b. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 212333 shall be a date that is not earlier than the latest expiration date of the patents-in-suit, including any extensions or exclusivities;
- c. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) and/or 35 U.S.C. § 283 permanently enjoining Upsher-Smith, Upsher-Smith's officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in concert or participation with Upsher-Smith or acting on Upsher-Smith's behalf, from engaging in

the commercial manufacture, use, offer to sell or sale within the United States, or importation into the United States, of any drug product covered by the patents-in-suit, including but not limited to Upsher-Smith's proposed generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg) prior to the latest expiration date of the patents-in-suit, including any extensions or exclusivities;

d. That a declaration be issued under 28 U.S.C. § 2201 that if Upsher-Smith, Upsher-Smith's officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in concert or participation with Upsher-Smith or on Upsher-Smith's behalf, engage in the commercial manufacture, use, offer for sale, sale and/or importation of Upsher-Smith's generic isotretinoin capsules, USP (10 mg, 20 mg, and 30 mg), prior to the latest expiration date of the patents-in-suit, it will constitute infringement of said patent;

e. That damages or other monetary relief be awarded to Plaintiffs under 35 U.S.C. §§ 271(a), (b), (c) and (e)(4)(C), and/or 35 U.S.C. § 284 as appropriate, and an accounting;

f. That this is an exceptional case under 35 U.S.C. § 285 and that Plaintiffs be awarded reasonable attorneys' fees and costs; and

g. That this Court award such other and further relief as it may deem just and proper.



Dated: January 30, 2019

Respectfully submitted,

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**CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1**

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: January 30, 2019

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**CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1**

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that plaintiffs seek, *inter alia*, injunctive relief.

Dated: January 30, 2019

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